DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

WARNING LETTER

NWE-15-99W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 22, 1999

Anthony N. Zarella
President
Boston Lobster Company, Inc.
345 West First Street
South Boston, MA 02127

Dear Mr. Zarella:

On February 2, 3, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 345 West First Street, South Boston, MA 02127. The investigator documented violations of Section 402 (a)(4) of the Federal Food Drug and Cosmetic Act and Title 21, Code of Federal Regulations (21CFR) Parts 110 "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food" (GMPs) and 123 "Safe and Sanitary Processing and Importing of Fish and Fishery Products" (Seafood HACCP Regulation), as follows:

As a Domestic Processor:

- Monitoring record data is missing, 21 CFR 123.6(c)(7). For example, your firm's HACCP plan for cooked lobstermeat states that the temperature of the cooking water and the length of cooking will be monitored at this critical cooking step. However, during the inspection, our Investigator observed that this was not being done.

Also, your plan indicates a CCP for the refrigerated storage step of your cooked lobster and states that the storage units temperature will be checked daily. There is no record of these required daily checks.

As an Importer:

- There are no written product specifications for live lobsters imported from Canada, 21 CFR 123.12(a)(2)(i).

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

FDA will not issue any FDA certificates of export for any of the seafood products processed at your facility until your firm is fully in compliance with the seafood HACCP regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675, Extension 113.

Sincerely,

John R. Marzilli
District Director
New England District Office